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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,917	01/16/2001	Mohamed M. Haq	650016-2	4854

58773 7590 07/26/2007

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	**PAPER NUMBER**
3626	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/760,917	HAQ, MOHAMED M.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-15,23,30-34 and 36-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-15, 23, 30-34, and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Request for Continued Examination (RCE) filed 5/7/07. Claims 1, 6-8, and 31-34 have been amended. Claims 1, 2, 4-15, 23, 30-34, and 36-38 remain pending.

Claim Objections

2. Claim 33 is objected to because of the following informalities: "the" should be inserted between "by" and "medical practitioner" at line 11. Appropriate correction is required.

3. Claim 33 is objected to because of the following informalities: at lines 13-14, the claim recites "comparing the new patient data...against the new patient data." Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 4-15, 23, 30-34, and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "seems inappropriate" in claims 1 and 33 is a relative term which renders the claim indefinite. The term "seems inappropriate" is not defined by

the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claims 1 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements/steps, such omission amounting to a gap between the elements/steps. See MPEP § 2172.01. It is unclear to the Examiner where the "known patient data and known medical information" are stored and accessed.

8. Claims 2, 4-15, 23, 30-32, 34, and 36-38 incorporate the deficiencies of claims 1 and 33, through dependency, and are also rejected.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-2, 4-8, 14-15, 30-34, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of McIlroy (5,583,758).

(A) Referring to claim 1, Leet discloses a computer system for assisting a medical practitioner, comprising (col. 19, lines 20-24 and Fig. 1 of Leet):

medical practitioner input means for receiving new patient data regarding a patient, a diagnosis regarding the patient, and a treatment plan for the patient from a medical practitioner (col. 18, lines 28-54 of Leet);

comparing the diagnosis and the treatment plan against the new patient data, known patient data and known medical information; and for generating an alarm in response to the comparison if the diagnosis or treatment plan seems inappropriate (col. 1, lines 5-11, col. 17, lines 15-20, and col. 4, lines 22-34 of Leet); and

second means for communicating any alarm to the medical practitioner, thereby enabling the physician to retrospectively consider the appropriateness of the diagnosis or treatment plan (col. 17, lines 15-20, col. 30, lines 32-38, and col. 1, lines 18-22 of Leet; the Examiner interprets "alerting" to be a form of "alarms").

Leet does not expressly disclose means for accessing a standard diagnosis database to obtain standard diagnosis criteria corresponding to the diagnosis input by the medical practitioner, the standard diagnosis criteria identifying standard criteria for deriving the diagnosis input by the medical practitioner, and to communicate the diagnosis criteria to the medical practitioner.

McIlroy discloses means for accessing a standard diagnosis database to obtain standard diagnosis criteria corresponding to the diagnosis input by the medical practitioner, the standard diagnosis criteria identifying standard criteria for deriving the diagnosis input by the medical practitioner, and to communicate the diagnosis criteria to the medical practitioner (col. 2, line 43 – col. 3, line 25, abstract, and Fig. 9b of McIlroy).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of McIlroy within Leet. The motivation for doing so would have been to more efficiently collect and evaluate health care data and for the diagnosis-based system to be used during various steps of the clinical decision process (col. 1, lines 52-55 and col. 2, lines 59-62 of McIlroy).

(B) Referring to claim 2, Leet does not expressly disclose wherein the first means comprises:

a suggest diagnosis means for accessing a suggested diagnosis database to retrieve a suggested diagnosis based on at least a portion of the new patient data; and

a check diagnosis means for comparing the diagnosis to the suggested diagnosis and for generating an alarm if there is a substantial difference.

McIlroy discloses a suggest diagnosis means for accessing a suggested diagnosis database to retrieve a suggested diagnosis based on at least a portion of the new patient data (Fig. 1 and col. 2, lines 43-48 of McIlroy); and

a check diagnosis means for comparing the diagnosis to the suggested diagnosis and for generating an alarm if there is a substantial difference (col. 8, lines 44-60 of McIlroy).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of McIlroy within Leet. The motivation for doing so would have been to reassess the decision-path provided by the system (col. 2, lines 29-30 of McIlroy).

(C) Referring to claim 4, Leet discloses wherein the treatment plan includes a prescription and the first means comprises:

a get drug data means for retrieving from a pharmacy one or more drugs in the prescription for the patient and from the known patient data identification of drugs that the patient is taking; and an interaction checking means for accessing a drug interaction database with (a) the one or more drugs in the prescription for the patient, (b) the drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner interprets "drug order" to be a form of "prescription" and "message" to be a form of "alarm").

(D) Referring to claim 5, Leet discloses wherein the interaction checking means comprises mitigating means for suggesting methods to mitigate the interaction; and alternative recommendation means for suggesting alternative drugs with no interaction (col. 25, lines 18-61 of Leet).

(E) Referring to claim 6, Leet discloses wherein the first means comprises:

a get patient data means for retrieving the known patient data; and

a find treatment means for accessing a treatment protocol database and using a subset of the new patient data and a subset of the known patient data to determine a recommended treatment protocol (abstract of Leet).

(F) Referring to claim 7, Leet discloses wherein the first means comprises:

a get patient data means for retrieving the known patient data; and

a treatment search means for accessing a treatment recommendation database and using a subset of the new patient data and a subset of the known

patient data to determine a treatment individualization recommendation (col. 12, line 50 – col. 13, line 1 of Leet).

(G) Referring to claim 8, Leet discloses wherein the treatment plan comprises a prescription and the first means comprises:

a get lab data means for obtaining laboratory results for the patient from a laboratory (col. 11, lines 36-40 of Leet); and

a find dosage means for using the laboratory results, a subset of the known patient data, the prescription and the new patient data in cooperation with a recommended dosage database to produce a recommended dosage for the prescription (col. 18, line 57 – col. 19, line 5 of Leet).

(H) Referring to claim 14, Leet discloses wherein the treatment plan comprises a prescription and the first means comprises:

a get drug data means for retrieving from a pharmacy one or more drugs prescribed for the patient and from the known patient data an identification of drugs that the patient is taking; and a drug cost means for accessing a drug cost database with (a) the one or more drugs prescribed for the patient, (b) the drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication that the patient is spending more on drugs than is necessary and to make a recommendation for a lower cost drug (col. 18, line 49 – col. 19, line 12 and col. 32, lines 35-49 of Leet).

(I) Referring to claim 15, Leet discloses wherein the first means comprises a check risks means for accessing a risk database to produce a risk reduction

recommendation for the patient (abstract, lines 1-9 of Leet; the Examiner interprets "rankings" to be a form of "recommendation").

(J) Referring to claim 30, Leet discloses wherein the first means has access to one or more of the following:

a drug interaction database (col. 18, line 49 – col. 19, line 12 of Leet);

a treatment protocol database (abstract, lines 1-4 of Leet);

a treatment recommendation database (col. 1, lines 9-11 of Leet);

a recommended dosage database (col. 18, line 67 – col. 19, line 5 of Leet);

a drug cost database (col. 32, lines 35-49 of Leet); and

a risk database (abstract, lines 1-9 of Leet).

Insofar as the claim recites "one or more of," it is immaterial whether or not all of the elements are disclosed.

(K) Referring to claim 31, Leet discloses further comprising an International Classification of Disease (ICD) determination means for processing a subset of the new patient data, a subset of the diagnosis and a subset of the treatment plan to determine an ICD (col. 1, lines 23-28, col. 7, lines 39-46, and Table 1 of Leet).

(L) Referring to claim 32, Leet discloses wherein the treatment plan comprises a prescription, an order, and an International Classification of Disease (ICD), and further comprising one or more of the following: a print prescription means for using the prescription to print a prescription form; an inform pharmacy means for using the prescription to inform a pharmacy of the prescription; a store data

means for storing the new patient data on a hospital computer; an enter order means for entering the order in a physician order entry system; and a save ICD means for saving the ICD in a business office (col. 18, line 49 – col. 19, line 18 and col. 34, lines 16-18 of Leet).

(M) Referring to claim 33, Leet discloses a computerized method for providing assistance to a medical practitioner, the method comprising (col. 19, lines 20-24 and Fig. 1 of Leet):

receiving new patient data regarding a patient, a diagnosis regarding the patient, and a treatment plan for the patient from a medical practitioner by a personal communicator (col. 24, lines 6-7 and col. 18, lines 28-54 of Leet);

comparing the new patient data, the diagnosis and the treatment plan against the new patient data, known patient data and against a medical database (col. 18, line 45 – col. 19, line 3 and col. 17, lines 15-24 of Leet);

generating an alarm to the medical practitioner in response to the comparison if the diagnosis or the treatment plan seems inappropriate (col. 17, lines 15-20 of Leet);

communicating any alarm to the medical practitioner, thereby enabling the physician to retrospectively consider the appropriateness of the diagnosis or treatment plan (col. 17, lines 15-20, col. 30, lines 32-38, and col. 1, lines 18-22 of Leet); and

enabling, through the personal communicator, the following actions:

initiating implementation of the treatment plan (col. 17, lines 20-28 and col. 18, lines 49-50 of Leet); and

allowing the medical practitioner to revise the diagnosis or treatment plan (col. 1, lines 5-11 and col. 17, lines 15-20 of Leet).

Leet does not expressly disclose using a standard diagnosis criteria database to determine standard diagnosis criteria, the standard diagnosis criteria identifying standard criteria for deriving the diagnosis input by medical practitioner, and communicating the standard diagnosis criteria to the medical practitioner.

McIlroy discloses using a standard diagnosis criteria database to determine standard diagnosis criteria, the standard diagnosis criteria identifying standard criteria for deriving the diagnosis input by medical practitioner, and communicating the standard diagnosis criteria to the medical practitioner. (col. 2, line 43 – col. 3, line 25, abstract, and Fig. 9b of McIlroy).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of McIlroy within Leet. The motivation for doing so would have been to more efficiently collect and evaluate health care data and for the diagnosis-based system to be used during various steps of the clinical decision process (col. 1, lines 52-55 and col. 2, lines 59-62 of McIlroy).

(N) Referring to claim 34, Leet discloses wherein initiating implementation of the treatment plan comprises one or more of the following printing a prescription; informing a pharmacy of the prescription; storing the new patient data, the diagnosis, and the treatment plan on a hospital computer; entering an order into

a physician order entry system; and saving an ICD in a business office (col. 34, lines 16-18 and col. 18, lines 54-66 of Leet).

(O) Referring to claim 36, Leet discloses wherein the step of comparing comprises the following actions: checking the appropriateness of prescribed medication; reviewing recommended treatment protocols; reviewing individualization recommendations; recommending dose adjustments; checking for adverse medication interactions; and checking the cost of prescribed medications (col. 3, lines 26-40 and col. 18, line 57 – col. 19, line 13 of Leet).

Insofar as the claim recites "one or more of," it is immaterial whether or not all of the elements are disclosed.

(P) Referring to claim 37, Leet discloses accepting clinical notes regarding the patient (col. 3, lines 36-40 of Leet).

11. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of McIlroy (5,583,758), and further in view of Portwood et al. (5,950,630).

(A) Referring to claim 9, Leet discloses wherein the treatment plan comprises a prescription and the first means comprises (col. 18, lines 49-57 of Leet):

a get drug data means for retrieving from a pharmacy one or more drugs prescribed for the patient and from the known patient data an identification of drugs that the patient is taking and foods the patient typically eats (col. 18, line

49 – col. 19, line 12 and Table IV of Leet; the Examiner interprets "diet" to be a form of "foods the patient typically eats"); and

an interaction checking means for accessing a database with (a) the one or more drugs prescribed for the patient, (b) the drugs that the patient is taking, and (c) the prescription and (d) the foods the patient typically eats, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 and Table IV of Leet; the Examiner interprets "drug order" to be a form of "prescription" and "message" to be a form of "alarm").

Leet and McIlroy do not disclose that there is a drug/food interaction database.

Portwood discloses drug-food interaction tests (col. 6, lines 63-67 of Portwood).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Portwood within Leet and McIlroy. The motivation for doing so would have been to ascertain if the drug regimen is within recommended ranges and to determine if any drug/food interaction problems exist (col. 6, lines 59-61 of Portwood).

(B) Referring to claim 10, Leet discloses wherein the interaction checking means includes a recommendation means for recommending a drug that will not have an interaction (col. 25, lines 18-61 of Leet).

12. Claims 11-13 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of McIlroy (5,583,758), and further in view of Evans (5,924,074).

(A) Referring to claim 11, Leet discloses wherein the treatment plan comprises a prescription and the first means comprises:

a get drug data means for retrieving from a pharmacy one or more drugs prescribed for the patient and from the known patient data identification of drugs that the patient is taking; and a checking means for accessing a database with (a) the one or more drugs prescribed for the patient, (b) the drugs that the patient is taking, and (c) the prescription, to produce an alarm if there is an indication of an interaction (col. 18, line 49 – col. 19, line 12 of Leet; the Examiner interprets "drug order" to be a form of "prescription" and "message" to be a form of "alarm").

Leet and McIlroy do not disclose a radiology/drug interaction database and radiology tests.

Evans discloses the usage of x-rays when prescribing medications (col. 5, lines 13-22 if Evans).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and McIlroy. The motivation for doing so would have been for the physician to obtain additional clinical data, such as x-rays before recommending a treatment plan (col. 5, lines 40-46 of Evans).

(B) Referring to claim 12, Leet and McIlroy do not disclose wherein the treatment plan comprises an order for X-rays and the first means comprises a check X-rays

means for obtaining laboratory results from a laboratory and for accessing an X-ray contraindication database with the laboratory results and the order for X-rays to produce a contraindication and to process the contraindication to produce an alarm.

Evans discloses wherein the treatment plan comprises an order for X-rays and the first means comprises a check X-rays means for obtaining laboratory results from a laboratory and for accessing an X-ray contraindication database with the laboratory results and the order for X-rays to produce a contraindication and to process the contraindication to produce an alarm (col. 5, lines 42-55, col. 12, lines 10-17 of Evans; the Examiner interprets "warning" to be a form of "alarm").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and McIlroy. The motivation for doing so would have been to alert the physician to investigate the effects of the treatment (col. 12, lines 17-19 of Evans).

(C) Referring to claim 13, Leet and McIlroy do not disclose wherein the check X-rays means processes the contraindication to produce a recommendation.

Evans discloses wherein the check X-rays means processes the contraindication to produce a recommendation (col. 12, lines 10-34 of Evans).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and McIlroy. The motivation for doing so would have been to allow the physician to investigate

the effects of the medication and select another medication from the list (col. 12, lines 10-34 of Evans).

(D) Referring to claim 38, Leet and McIlroy do not disclose wherein accepting the clinical notes comprises recording a spoken rendering of the clinical notes.

Evans discloses wherein accepting the clinical notes comprises recording a spoken rendering of the clinical notes (col. 9, lines 1-4 of Evans; the Examiner interprets "physician's dictation" to be a form of "spoken rendering of the clinical notes").

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Evans within Leet and McIlroy. The motivation for doing so would have been to include patient data in a variety of data types generated by healthcare providers (col. 8, lines 65-66 of Evans).

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leet (6,000,828) in view of McIlroy (5,583,758), and further in view of Barry et al. (6,081,786).

(A) Referring to claim 23, Leet and McIlroy do not disclose further comprising a personal communicator including a display having a red alert area, where alarms regarding the potential for a major adverse effect are displayed; and a yellow alert area, where alarms regarding the potential for a minor effect or need for closer monitoring are displayed.

Barry discloses a personal communicator including a display having a red alert area, where alarms regarding the potential for a major adverse effect are

displayed; and a yellow alert area, where alarms regarding the potential for a minor effect or need for closer monitoring are displayed (col. 14, lines 16-22 & 43-47 of Barry).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Barry within Leet and McIlroy. The motivation for doing so would have been to provide an instant graphical warning level (col. 14, lines 42-43 of Barry).

Response to Arguments

14. Applicant's arguments filed 5/7/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 5/7/07.

(1) Applicant argues that the applied references do not teach accessing or communicating standard diagnosis criteria.

(A) As per the first argument, when referring to Applicant's specification, there is no definition of "standard diagnosis criteria" given with precision, clarity, and deliberateness to warrant the meanings currently argued by Applicant. For example, Applicant's definition of "standard diagnosis criteria" at page 12, lines 16-18 of the specification contains non-committal phraseology such as "preferably." As such, the Examiner respectfully submits that the broadest reasonable interpretation of the term "standard diagnosis criteria" would include diagnosis-based guidelines, which is precisely disclosed by McIlroy (note col. 2,

lines 59 – 65 of McIlroy).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a method and system aiding medical diagnosis and treatment (5,974,124); and a universal computer assisted diagnosis (6,021,404).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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